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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,193	01/25/2002	Hyune Hwan Lee	1544.03	2887

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/048,193	LEE ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4 and 6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed February 9, 2005 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 1, 2, 4 and 6 are pending.

Applicants' amendment filed February 9, 2005 is acknowledged. Applicants' response has been fully considered. Claims 1, 4 and 6 have been amended. Thus, claims 1, 2, 4 and 6 are examined.

Objection Withdrawn

3. The previous objection to Fig. 2 regarding the letters in the drawing being too small and the nucleotide sequence shown in Fig. 2 but without providing "SEQ ID NO:" is withdrawn in view of applicants' submission of a substitute Fig. 2 and a Sequence Listing, where CRF has been entered.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

4. The previous rejection of claims 1, 2, 4 and 6 under 35 U.S.C. 112, second paragraph, regarding the cited term "resulting from homologous recombination through AcMNPV and AcNPV site" is withdrawn in view of applicants' amendment to the claim and applicants' response at page 2 in the amendment filed February 9, 2005.

Claim Rejections - 35 USC § 103

5. The previous rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Naidu *et al.* (Antimicrobial Agents and Chemotherapy 240-245 (1993)) taken with Li *et al.* (U.S.

Patent 5,861,238, January 19, 1999), is withdrawn in view of applicants' amendment to the claim and applicants' response at page 3 in the amendment filed February 9, 2005.

Objection to New Matter Added to Specification

6. The amendment filed February 9, 2005 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The original Fig. 2 and the specification (see page 5, lines 18-26; page 8, line 24-page 9, line 7) do not indicate human lactoferrin gene having 2.1 kb is inserted into a specific "pT3T3 18U vector" to form recombinant plasmid pT7T3-hLf having 4.1 kb, the partial nucleotide sequence of pBacPAK8, and the recombinant expression vector pBacPAK-hLf having 7.7kb (the original pBacLf having 7.6 kb), while the newly submitted Fig. 2, the specification amendment (pages 1-4 in the response) and the amended claims 1 and 4 recite the new matters.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2, 4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 2, 4 and 6 are directed to a method for producing human lactoferrin using an insect cell, a recombinant insect virus, and a biological verification method for a recombinant lactoferrin. The specification only indicates human lactoferrin is produced by a method using an insect cell comprising the step of combining a transfer vector with a recombinant plasmid phLf-8 to prepare a recombinant expression vector pBacLf which is modified having a polyhedrin promoter to regulate lactoferrin gene (page 5, line 18-page 6, line 9; original Fig. 2), however, it does not disclose the recombinant plasmid phLf-8 is pT7T3-hLf and is constructed by inserting human lactoferrin gene with 2.1 kb into pT7T3 18U backbone, the partial nucleotide sequence of pBacPAK8, and the recombinant expression vector pBacPAK-hLf having 7.7 kb as indicated in the newly submitted Fig. 2, the specification amendment (pages 1-4 in the response) and the amended claims 1 and 4. Furthermore, the original pBacLf has 7.6 kb instead of 7.7 kb (see original Fig. 2), there is no indication in the original specification that pT7T3 18U backbone (pharmacia Co.) has been used. The lack of description of construction of recombinant plasmid phLf-8 using pT7T3 18U backbone, and the recombinant expression vector pBacPAK-hLf having 7.7 kb, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

In response, applicants indicate the pT3T3 18U vector is a well-known vector being used widely as cloning CDNA, and it was added for explaining the prior art of producing a recombinant plasmid and was not claimed as the invention. That is, in order to produce'

recombinant expressing vector, combining a transfer vector (pBacPAK8) with a recombinant plasmid is needed, where the recombinant plasmid should include a 2.1kb full gene including the start codon and the signal sequence of the human lactoferrin. Therefore, the information about the vector used to produce the recombinant plasmid is not important, and thus the information on the lactoferrin gene and the restriction enzyme (HindIII and Sal I) was disclosed only for explaining the recombinant plasmid. Therefore, one skilled in the art is supposed to be able to produce the recombinant plasmid even with the disclosure in the original Fig. 2 (pages 2-3 of the response).

Applicants' response has been considered, however, the argument is not found persuasive because the original specification including original Fig. 2 does not describe the construction of recombinant plasmid phLf-8 using pT7T3 18U backbone and 2.1 kb lactoferrin gene, and the recombinant expression vector pBacPAK-hLf having 7.7 kb as indicated in the newly submitted Fig. 2 and the specification amendment (pages 1-4), thus a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 4 is indefinite because of the use of the term "to produce a recombinant expression vector pBacPAK8 modified to permit the regulation of a lactoferrin gene by a polyhedrin

promoter in a vector pBacPAK8". The cited term renders the claim indefinite, it is not clear how the recombinant expression vector which contains human lactoferrin gene would be the same as the transfer vector, pBacPAK8.

10. Claim 6 is indefinite as to "A biological verification method for a recombinant human lactoferrin", it is not clear how the recombinant lactoferrin is verified as a human lactoferrin since the method only recites measuring the anti-bacterial activity of the protein, it does not contains the step of verifying the protein as recombinant human lactoferrin.

In response, applicants indicate the claimed method is directed to verify the biological activity of the recombinant human lactoferrin. Verifying the recombinant lactoferrin as the human lactofenin includes three stages of transcription, translation, and effect. The invention claims the method of verifying the effect, and verification of the transcription by RT-PCR and the translation using the antibody to the human lactoferrin has been described in prior arts (page 3 of the response).

The response has been considered, however, the argument is not found persuasive because the claim does not indicate the claim is directed to verifying "the biological activity" of lactoferrin, it reads a verification method for a recombinant human lactoferrin, which includes verifying the protein as human lactoferrin.

Conclusion

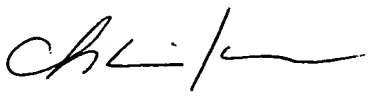
11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CMK
March 3, 2005